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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,923	01/04/2002	Stephen Martone	501060.01	3782

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DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
SUITE 3400
1420 FIFTH AVENUE
SEATTLE, WA 98101

EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,923

Applicant(s)

MARTONE ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 9, 11, 24, 26, 27, 29, 40 and 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7, 8, 10, 12-23, 25, 28, 30-39 and 41-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Embodiment VI shown in Figure 10 in Paper Filed on 2/17/2004 is acknowledged. Claims 3 – 6, 9, 11, 24, 26, 27, 29, 40 and 55 – 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Information Disclosure Statement

The information disclosure statements filed 1/4/02 and 10/27/03 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 5 does not show the distal end 124 as disclosed on page 7, line 18. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 17, 33 and 47 are objected to because of the following informalities: Line 3 states "first direct". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 7, 8, 19, 21, 34, 35, 38, 39, 48, 50 – 52 and 54 are rejected under 35

U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,793,326 to Shishido.

In regards to claims 1, 2, 7, 8, 19, 21, 34, 35, 38, 39, and 48, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). The sampling device comprises a brush member (Col. 6, lines 31 – 40) and is attached to the body portion of the sheath. The brush member has a contoured shape and would partially conform to the curvature of the insertion tube because of the resilient nature of the bristles. The sheath has a channel extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube (Figure 6). The sheath is adapted to tightly surround a distal portion of the insertion tube.

In regards to claims 50 – 52 and 54, Shishido discloses a method for obtaining a sample from a target within a body, the body being a tube or the like, including providing an endoscopic assemble including a sheath having a sampling device attached thereto (Col. 6, lines 1 – 6), the sampling device having a collection member proximate the distal end of the assembly; inserting the

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collection member into the body; engaging the collection member with the target; and removing the collection for the body (Col. 6, line 61 – Col. 7, line 9). The assemble comprises an insertion tube and at least part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Figure 6). Shishido discloses the collection member being a brush (Figure 7).

6. Claims 1, 2, 7, 8, 19, 21, 34, 35, 38, 39, 48, 50 – 52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,301,061 to Nakada et al.

In regards to claims 1, 2, 7, 8, 19, 21, 34, 35, 38, 39, and 48, Nakada et al. discloses a sheath (Figure 14) assembly adapted for use with an endoscopic insertion tube including a sheath (9) having a body portion adapted to partially encapsulate the working end of the insertion tube (2) and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube; and a collection member (41) attached to the sheath and including a collection member proximate the distal end portion. The sampling device comprises a brush member and is attached to the body portion of the sheath (Col. 7, lines 5 – 12). The brush member has a contoured shape and would partially conform to the curvature of the insertion tube because of the resilient nature of the bristles. The sheath has a channel extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube (Col. 7, lines 13 – 16). The sheath is adapted to tightly surround a distal portion of the insertion tube.

In regards to claims 50 – 52 and 54, Nakada et al. discloses a method for obtaining a sample from a target within a body, the body being turbine, boiler, engine or the like, including providing an endoscopic assemble including a sheath (9) having a sampling device (41) attached thereto, the sampling device having a collection member proximate the distal end of the assembly; inserting the collection member into the body; engaging the collection member with the target; and removing the

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collection for the body (Col. 7, lines 5 – 12). The assemble comprises an insertion tube and at least part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Col. 7, lines 13 – 16). Nakada et al. discloses the collection member being a brush.

7. Claims 1, 2, 19 – 21, 34, 35 and 48 – 52 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,699,178 to Koda.

In regards to claims 1, 2, 19 – 21, 34, 35, 48 and 49, Koda discloses a sheath assembly (Figure 5) adapted for use with an endoscopic insertion tube including a sheath having a body portion (50) adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 4, lines 25 – 27); and a collection member (55) attached to the sheath and including a collection member proximate the distal end portion (Col. 4, line 45). The sheath has a channel (52) extending longitudinally along part of the body portion and having an opening adapted to be proximate the distal end of the insertion tube when the sheath assembly is positioned on the insertion tube. The sheath is adapted to tightly surround a distal portion of the insertion tube. Koda discloses an elastomeric body portion (Col. 4, line 32).

In regards to claims 50, 51 and 52, Koda discloses a method for obtaining a sample from a target within a body including providing an endoscopic assemble including a sheath (50) having a sampling device (55) attached thereto, the sampling device having a collection member proximate the distal end of the assembly; inserting the collection member into the body; engaging the collection member with the target; and removing the collection for the body. The assembly comprises an insertion tube and at least part of the insertion tube is encapsulated by a sheath having the sampling device attached thereto (Col. 4, lines 32 – 45).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 10, 12, 13, 16 – 18, 41 – 43, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 1 and 34 above, in view of U.S. Patent No. 6,551,278 to Geitz and further in view of U.S. Patent No. 5,899,850 to Ouchi.

In regards to claims 10, 12, 13, 16 – 18, 41 – 43, 46 and 47, Shishido discloses an endoscopic system having a collection member comprising a brush (Col. 6, lines 31 – 40), but fails to disclose a cover member being attached to the sheath and being movable between a first positioning at partially covering the collection member and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member including an actuator extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member. Geitz teaches an endoscopic system having a cover member (8) attached to the system and being movable between a first positioning at partially covering the distal tip and a second position at least partially exposing the distal tip. The cover member including an actuator (10) extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member (Col. 6, lines 44 – 51). Ouchi discloses an endoscopic system having a collection member comprising a brush (2). Ouchi discloses a cover member that surrounds the brush while it

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is not in use to protect the brush and any collected material (Col. 2, lines 4 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as disclosed by Shishido to include a moveable cover member as taught by Geitz in order to protect the brush and any collected material as taught by Ouchi (Col. 2, lines 4 – 10).

10. Claims 22, 23, 25, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 6,551,278 to Geitz and further in view of U.S. Patent No. 5,899,850 to Ouchi.

In regards to claims 22, 23, 25, 28, 32 and 33, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). The sampling device comprises a brush member (Col. 6, lines 31 – 40) and is attached to the body portion of the sheath. However, Shishido fails to disclose a cover member being attached to the sheath and being movable between a first positioning at partially covering the collection member and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member including an actuator extending along at least a part of the body portion, the actuator being moveably coupled in a first and second direction to the body portion for actuating the cover member. Geitz teaches an endoscopic system having a cover member (8) attached to the system and being movable between a first positioning at partially covering the distal tip and a second position at least partially exposing the distal tip. The cover member including an actuator (10) extending along at least a part of the body portion, the actuator being moveably coupled in a first

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and second direction to the body portion for actuating the cover member (Col. 6, lines 44 – 51).

Ouchi discloses an endoscopic system having a collection member comprising a brush (2). Ouchi discloses a cover member that surrounds the brush while it is not in use to protect the brush and any collected material (Col. 2, lines 4 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as disclosed by Shishido to include a moveable cover member as taught by Geitz in order to protect the brush and any collected material as taught by Ouchi (Col. 2, lines 4 – 10).

11. Claims 12 – 15, 41 and 43 – 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 1 and 34 above, and in view of U.S. Patent No. 5,603,699 to Shine.

In regards to claims 12 – 15, 41 and 43 – 45, Shishido discloses a sharp collection member (Col. 6, line 61 – Col. 7, line 5) but fails to disclose a cover member attached to the device proximate the collection member to at least partially cover the collection member. Shishido fails to disclose the cover member being movable between a first position partially covering the collection member, and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member being hingeably attached to the device and biased into the first position. Shine discloses a hinged cover member for sharp collection members being positioned proximate the sharp member and movable between a first and second position covering and exposing the member respectively (Col. 2, line 65 – Col. 3, line 6). Shine discloses the cover member being biased into the first position (Col. 6, lines 5 – 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Shishido to include a cover member as taught by Shine in order to protect the user from accidental puncture (Col. 1, lines 5 – 10).

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12. Claims 22, 25, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,603,699 to Shine.

In regards to claims 22, 25, 30 and 31, Shishido discloses a sheath assembly adapted for use with an endoscopic insertion tube including a sheath (Col. 6, lines 1 – 6) having a body portion adapted to partially encapsulate the working end of the insertion tube and having a distal end adapted to be proximate the working end when the sheath assembly is positioned on the insertion tube (Col. 6, lines 6 – 12); and a collection member attached to the sheath and including a sharp collection member proximate the distal end portion (Col. 6, line 61 – Col. 7, line 9). However, Shishido fails to disclose a cover member attached to the device proximate the collection member to at least partially cover the collection member. Shishido fails to disclose the cover member being movable between a first position partially covering the collection member, and a second position at least partially exposing the collection member. Shishido fails to disclose the cover member being hingeably attached to the device and biased into the first position. Shine discloses a hinged cover member for sharp collection members being positioned proximate the sharp member and movable between a first and second position covering and exposing the member respectively (Col. 2, line 65 – Col. 3, line 6). Shine discloses the cover member being biased into the first position (Col. 6, lines 5 – 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Shishido to include a cover member as taught by Shine in order to protect the user from accidental puncture (Col. 1, lines 5 – 10).

13. Claims 36, 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 34 and 53 above, and in view of U.S. Patent No. 5,337,734 to Saab.

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In regards to claims 36, 37 and 53, Shishido discloses a sheath assembly (Col. 6, lines 1 – 6) for use with an endoscope having an outer peripheral surface and a sampling device attached to the outer surface (Figure 6), but fails to disclose the sheath having an enclosed distal end. Saab teaches a sheath assembly for use with an endoscope having an enclosed distal end. It would have been obvious to one having ordinary skill in the art to modify the sheath as disclosed by Shishido to include an enclosed distal end as taught by Saab in order to eliminate problems of cleaning and sterilizing the endoscope between uses (Col. 1, lines 18 – 26).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,746,692 to Bacich et al. discloses endoscopic sheath having attached instrument.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R

JMLF

May 17, 2004

Robert L. Masser

ROBERT L. MASSER
PRIMARY EXAMINER